

## REMARKS

The Official Action of November 21, 2003 has been carefully considered and reconsideration of the application as amended is respectfully requested.

The claims have been amended to remove the bases for the rejections to the claims under 35 USC 112, second paragraph. With specific respect to the rejection on the basis that it is allegedly unclear as to whether the polyacrylamide gel is polymerized or unpolymerized, it is respectfully considered that, by definition, the term "**polyacrylamide gel**" refers to the polymerized product. All claims as amended are believed to be sufficiently definite to satisfy the dictates of 35 USC 112, second paragraph.

The claims have also been amended to remove the bases for the rejections under 35 USC 112, first paragraph, and the objections relating to the presence of alleged new matter. In this respect, the claims have been limited to the implantation of the polyacrlamide gel for the formation of connective tissue around the implanted gel. The Examiner has acknowledged that the claims so limited are supported by the specification as filed. Moreover, the claims reciting that the transplanted cells are viable for a specific period of time (for up to 100 days) have been canceled and replaced with new claims 42-45 which recite that the transplanted cells are viable for a period that exceeds the period that the transplanted cells would be viable without prior formation of the connective tissue capsule. This is in accordance with the

specification as filed at, for example, page 3, last paragraph to page 4, second paragraph.

Although it is believed that all of the rejections under 35 USC 112, first paragraph, have been removed by amendment to the claims, Applicants also submit herewith two (2) declarations under 37 CFR 1.132, which show that one of skill in the art could practice the invention as claimed, in accordance with the teachings in the specification as filed, without undue experimentation. These declarations are the Declaration Under 37 CFR 1.132 of Vladimir Konstantinovich Sologub (one of the co-inventors) and the Declaration Under 37 CFR 1.132 of Oleg Vladimirovich Matorin. From the declarations, it is clear that the specification is enabling for the invention as now claimed.

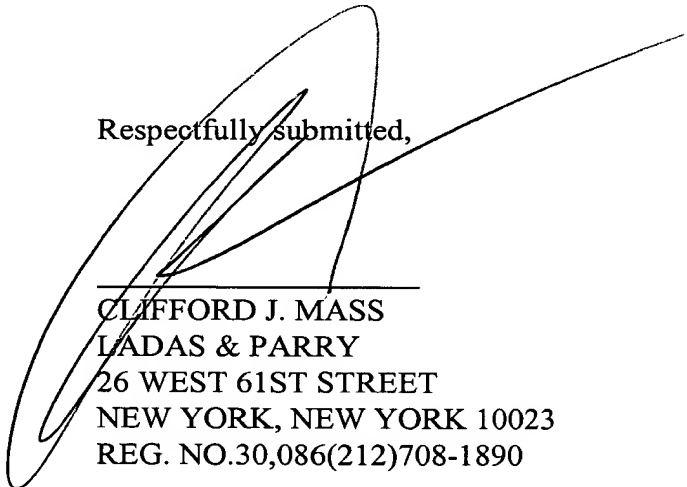
Claim 24 stands rejected under 35 USC 102(b) as allegedly being anticipated by Lamberti. Claims 24-29 stand rejected under 35 USC 103(a) as allegedly being unpatentable over Lamberti in view of Chaikof, and Sefton and Stevenson. Applicants respectfully traverse these rejections.

As discussed in the Sologub Declaration at paragraphs 8-9, the claimed invention differs substantially from the cited art in a number of respects. Among other things, the claims as amended require that the polyacrylamide gel be introduced into the tissue of a mammal with the formation of a connective tissue capsule *in vivo* and with insertion of transplanted cells into the capsule only thereafter. In contrast,

the cited references describe the *ex vivo* encapsulation of cells at the polymerization stage (see Sologub Declaration at paragraphs 8-9). It may thus be appreciated that, even assuming for the sake of argument that the references were properly combinable, the combination would not arrive at the claimed invention. Accordingly, it is respectfully submitted that the references cannot be considered to set forth even a *prima facie* case of obviousness for the invention as now claimed. Moreover, even assuming for the sake of argument that the references could set forth a *prima facie* case, the evidence of record in the Declarations submitted herewith shows unexpected results that would be sufficient to overcome such *prima facie* case.

In view of the above, it is respectfully submitted that all rejections and objections of record have been overcome and that the application is now in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,



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